

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference PTD/JPS/2731PC	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/GB2005/001577	International filing date ( <i>day/month/year</i> ) 26 April 2005 (26.04.2005)	Priority date ( <i>day/month/year</i> ) 27 April 2004 (27.04.2004)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant SMITH & NEPHEW, PLC			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 8 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input checked="" type="checkbox"/>	Box No. II	Priority
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

		Date of issuance of this report 01 November 2006 (01.11.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70		Authorized officer  Nora Lindner  e-mail: pt02@wipo.int

# PATENT COOPERATION TREATY

REC'D 30 AUG 2005

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PCT

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

5/11

PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

		Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)
Applicant's or agent's file reference see form PCT/ISA/220		<b>FOR FURTHER ACTION</b> See paragraph 2 below
International application No. PCT/GB2005/001577	International filing date (day/month/year) 26.04.2005	Priority date (day/month/year) 27.04.2004
International Patent Classification (IPC) or both national classification and IPC A61M1/00, A61M3/02, A61M27/00		
Applicant SMITH & NEPHEW, PLC		

### 1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Lakkis, A Telephone No. +31 70 340-4136	
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**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
 This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material:  
 in written format  
 in computer readable form
  - c. time of filing/furnishing:  
 contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. II Priority**

1.  The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2.  This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,  
 claims Nos. 10

because:

the said international application, or the said claims Nos. 10 relate to the following subject matter which does not require an international preliminary examination (*specify*):  
**see separate sheet**

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the whole application or for said claims Nos. 10

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	<input type="checkbox"/> has not been furnished <input type="checkbox"/> does not comply with the standard
the computer readable form	<input type="checkbox"/> has not been furnished <input type="checkbox"/> does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See separate sheet for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2005/001577

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or  
industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	2-4, 6-8
	No: Claims	1,5,9
Inventive step (IS)	Yes: Claims	
	No: Claims	1-9
Industrial applicability (IA)	Yes: Claims	1-9
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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**Box No. VI Certain documents cited**

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1. Certain published documents (Rules 43bis.1 and 70.10)  
and / or
2. Non-written disclosures (Rules 43bis.1 and 70.9)

**see form 210**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

Re Item III.

Rules 39.1(iv) and 67.1(iv) PCT - Method for treatment of the human or animal body by therapy

Re Item V.

1 Reference is made to the following documents:

- D1 : WO 84/01904 A (SWANBECK, GUNNAR) 24 May 1984 (1984-05-24)
- D2 : US 2003/171675 A1 (ROSENBERG LIOR) 11 September 2003 (2003-09-11)
- D3: WO 2005/051461 A (SMITH & NEPHEW PLC; BLOTT, PATRICK, LEWIS; GREENER, BRYAN; HARTWELL, E) 9 June 2005 (2005-06-09)
- D4: WO 2004/037334 A (SMITH & NEPHEW PLC; BLOTT, PATRICK, LEWIS; GREENER, BRYAN; HARTWELL, E) 6 May 2004 (2004-05-06)
- D5: WO 00/50143 A (NXSTAGE, INC) 31 August 2000 (2000-08-31)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 is not new in the sense of Article 33(2)PCT.

Note: the term "means for stressing the wound bed" is very broad, for this reason D1 falls under the wording of claim 1:

Document D1 (page 2, last paragraph-page 3, 1st paragraph; figure 1), discloses (the references in parentheses applying to this document):

An apparatus for irrigating, flow stressing and/or cleansing wounds comprising a fluid flow path comprising a conformable dressing (10) having a backing layer, at least one

inlet (11) and one outlet (12) pipe, a means for fluid cleansing (14), a fluid reservoir (15), a device for moving fluid (13), means for stressing the wound bed (see page 3, lines 7-17; the circulating liquid, the pressure difference and the fixation means on the skin all can be considered as stressing the wound bed), such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube and recirculated by the device through the flow path.

**3 INDEPENDENT CLAIM 9**

The same as above applies mutatis mutandis to claim 9, which, for the same reasons, is considered as not new in view of D1 (Article 33(2) PCT).

**4 DEPENDENT CLAIMS 2-8**

Dependent claims 2-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

The subject-matter of dependent claim 2 differs from the disclosure of D1 in that it further comprises means for applying a varying pressure. The problem to be solved by this feature may be regarded as improving healing.

D2 (paragraphs 3, 47-52, figure 1) discloses an apparatus for irrigating, flow stressing and/or cleansing wounds which comprises means for applying a varying pressure, namely high frequency vibrations, to the wound bed, where the same feature is used for solving the same problem (improving healing). Therefore the features disclosed in D1 and D2 would be combined by the skilled person, without exercise of any inventive skills, in order to solve the problem posed. Moreover, it is noted that the two aspects of i) cleaning the recirculating fluid and ii) applying varying pressure solve two unrelated problems (reusing the fluid and improving healing, respectively) and therefore are considered as a juxtaposition of known features with no synergetic effect. For all these reasons, the subject matter of claim 1 cannot be considered as involving an inventive step (Article 33(3) PCT).

Claims 3, 4 represent known constructional alternatives, for claim 5, see D1. For claims 6-8, see D5 (abstract) and the argumentation regarding claim 2 concerning juxtaposition of unrelated features.

**Re Item VI.**

Late document D3 (see the whole document and especially page 15, lines 21-24, page 16, lines 9-13, page 30, lines 19-25, page 45, lines 22-25, figure 5) and intermediate document D4 (see the whole document, especially page 31, lines 23-29) may also become pertinent for questions of novelty and of validity of priority.

**Re Item VIII.**

The application does not meet the requirements of Article 6 PCT, because claims 1, 7, 8 are not clear:

- a) In claim 1, the words "characterised in that" appear two times in the claim, lines 4 and 29; the first time was thus disregarded
- b) In claim 1, the text followed by "optionally or as necessary" (lines 23-24, 26, 33-34) as well as the optional feature under d) (line 28) and part of e) (lines 30-31), were considered as completely optional for the interpretation of the claim. Same in claim 9, line 20.
- c) Claims 7 and 8 should be dependent on claim 6 (and not on claim 3), since they refer to "the other fluid" defined only in claim 6.